EXHIBIT 72

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

In re LIDODERM ANTITRUST LITIGATION	Master File No. 14-md-02521-WHO MDL No. 2521
THIS DOCUMENT RELATES TO: END-PAYOR PLAINTIFF ACTIONS	**END-PAYOR PLAINTIFFS' PROPOSED TRIAL MANAGEMENT PLAN**

I. INTRODUCTION

End-Payor Plaintiffs ("Plaintiffs") have moved to certify a Class of end-payor purchasers of Lidoderm and generic Lidoderm. Plaintiffs submit this proposed Trial Management Plan outlining how they will intend to prosecute the antitrust claims of the proposed Class at trial.[1]

"[T]o establish an antitrust claim, plaintiffs typically must prove (1) a violation of antitrust laws, (2) an injury they suffered as a result of that violation, and (3) an estimated measure of damages." *In re High-Tech Emp. Antitrust Litig.*, 985 F. Supp. 2d 1167, 1183 (N.D. Cal. 2013). Plaintiffs propose a three-phase process for establishing these elements and allocating damages among the members of the Class. In Phase I, Plaintiffs will present to the jury evidence of the first two elements of their antitrust claims: violation of antitrust laws and impact. Assuming liability is established in Phase I, in Phase II, the jury will determine the amount of aggregate damages owed by Defendants. After trial, in Phase III, damages will be apportioned to individual members of the Class. At that time, Plaintiffs expect to present a Claims Administration Protocol that will set forth proposed procedures for the submission, processing, and resolution of individual Class members' claims. The Court will be asked to approve the Claims Administration Protocol and then direct entry of a final judgment reflecting the results of all three Phases.

II. DETAILS OF TRIAL MANAGEMENT PLAN

A. Phase I: Proof of Liability with Common Evidence

In Phase I Plaintiffs will present common evidence to prove the first two elements of their antitrust claims: antitrust violation and impact. Plaintiffs' state antitrust claims are substantially the same and require overlapping proof (*see* Declaration of Dena C. Sharp, Ex. 71). A single jury will therefore hear evidence on core issues that, once proven, will concurrently establish a violation of each state law under which Plaintiffs have brought their claims. And because the state statutes under which Plaintiffs bring their claims are interpreted in conformity with the Direct Purchasers' federal

[1] Plaintiffs reserve the right to suggest changes to this Trial Management Plan in advance of trial in light of additional discovery, reports from experts, changes in law, and/or orders entered by the Court.

Sherman Act claims, Plaintiffs' and Direct Purchasers' claims can be jointly prosecuted in a single trial.

Phase I will include:

1. **Preliminary Instructions to the Jury**

At the commencement of both Phase I and Phase II, jurors will be provided with a summary of the key legal factual and legal issues that will be at issue during the trial. *Manual for Complex Litigation (Fourth)* § 12.432 (2004). Although the final instructions given to the jurors at the end of each phase will govern the jurors' deliberations, the preliminary instructions will orient the jurors to the evidence they will see and hear throughout trial.

2. **Opening Arguments**

The parties will present opening arguments regarding the core liability issues that are common to Plaintiffs' antitrust and consumer protections claims.

3. **Presentation of Evidence of Antitrust Violation and Impact**

Antitrust Violation: Plaintiffs will prove that Defendants entered into an agreement to delay the entry of Watson's generic Lidoderm product and the release of Endo's competing authorized generic. Plaintiffs' evidence will demonstrate, among other things, that:

- Defendants intended for their agreement to prevent the risk of competition from less-expensive generic versions of Lidoderm;
- Watson was ready and able to launch generic Lidoderm as early as August 23, 2012;
- Watson agreed to, and did in fact, delay the launch of its generic Lidoderm product;
- Defendants' agreement has no countervailing procompetitive justifications;
- Any proffered procompetitive justifications were not reasonable necessary to accomplish their goals; and
- The relevant market is Lidoderm and AB-rated generic versions of Lidoderm.

Antitrust Impact and Injury: Plaintiffs will also prove that Defendants' agreement impacted Plaintiffs and proximately caused their injuries by forcing them to pay higher prices for branded and generic Lidoderm than they would have absent Defendants' illegal agreement to delay the availability of less-expensive generic versions of Lidoderm. Plaintiffs' evidence will demonstrate that:

- Generic drugs are significantly less expensive than the branded version of the same drug product;
- Purchasers pay significantly less for generic drugs than they do for branded drugs;
- The presence of a second generic drug product on the market – such as an authorized generic – further drives down branded and generic drug prices;
- State laws and health benefit plans promote or require the substitution of less expensive generic drugs for branded versions once the generic drug products are on the market;
- Defendants' agreement delayed the availability of, and competition from, generic Lidoderm;
- Defendants understood that Watson could have launched its generic Lidoderm product at a significantly lower price than that of Endo's and Teikoku's branded product;
- Defendants' conduct impacted all or nearly all Class members; and
- The pricing of Lidoderm and generic Lidoderm once Watson launched its generic Lidoderm product confirm the impact of Defendants' agreement.

All of the evidence Plaintiffs will present to prove antitrust violation and impact will come from sources common to the Class, including Defendants' documents and internal communications, records of the parties' settlement negotiations, Defendants' testimony, and expert testimony.[2]

4. **Closing Arguments**

The parties will present closing arguments summarizing the evidence presented throughout trial and the main issues that the jury will be asked to decide.

5. **Final Instructions and Special Verdict Forms**

Jurors will be provided with jury instructions and make factual findings for all of Plaintiffs' claims by answering questions on special verdict forms. Jury instructions tracking Section 1 of the Direct Purchasers' Sherman Act claims will encompass all of the elements of Plaintiffs' state law claims, allowing the jury to make findings that will be equally applicable to all plaintiffs' claims. *See*, *e.g.*, *In re Static Random Access Memory (SRAM) Antitrust Litig.*, No. 4:07-md-01819 (N.D. Cal. Dec. 3, 2010) (ECF No. 1189) (proposed joint jury instructions for direct purchasers under

[2] During trial jurors will be allowed to take notes and retain their notebooks for use in post-trial deliberations. MCL, §§ 12.421, 12.422. The notebooks will assist the juror in organizing the large amount of information and exhibits the parties will present throughout trial.

federal antitrust law and indirect purchasers under state law) (excerpts attached as Exhibit A); *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 1:12-md-02409-WGY (D. Mass. Oct. 14, 2014) (ECF No. 1051) (proposed preliminary jury instructions for phase I of trial on behalf of all plaintiffs) (attached as Exhibit B).

The following are examples of the questions that will likely be included on the special verdict forms:

- Did Defendants reach an agreement delaying competition in the Lidoderm market?
- Did Defendants' agreement have the effect of artificially maintaining and inflating the price of Lidoderm and generic Lidoderm?
- Did Defendants' agreement impact Plaintiffs and members of the class by forcing them to pay more for Lidoderm and generic Lidoderm than they would have in the absence of Defendants' agreement?
- Absent the agreement, would a generic version of Lidoderm have come to the market before September 15, 2013?
- If so, what is a reasonable estimate as to when?
- Would an authorized generic have entered at or about the same time?

B. Phase II: Establishing Aggregate Damages the Class

Based on the answers given by the jury in response to the special verdict questions in Phase I, the Court will determine under which states' laws Plaintiffs have established liability. In Phase II, Plaintiffs will present classwide proof of aggregate damages for purchases made in each state. The "use of aggregate damages calculations is well established in federal court" in antitrust cases in general, and in pay-for-delay cases in particular, and is "implied by the very existence of the class action mechanism itself.'" *In re Nexium (Esomeprazole) Antitrust Litig.*, 297 F.R.D. 168, 182 (D. Mass 2013) (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 197 (1st Cir. 2009)).

Common evidence will also demonstrate that Defendants' conduct warrants treble or increased damages as appropriate under state laws.

Phase II will include:

1. **Opening Arguments**

The parties will present opening arguments regarding their methodologies for determining aggregate damages, including which inputs should be used to inform those analyses and generate a damages figure.

2. **Presentation of Evidence Regarding Aggregate Damages**

Plaintiffs will present documentary evidence and expert analysis establishing the aggregate amount of Class damages on a state-by-state basis. Plaintiffs' evidence will demonstrate:

- The rate at which Watson's generic Lidoderm product and Endo's and Teikoku's authorized generic would have taken market share from branded Lidoderm;
- The prices of generic and branded Lidoderm that would have prevailed in the absence of Defendants' anticompetitive agreement;
- The number of units of Lidoderm purchased during the Class period;
- The percentage of purchases made by uninjured Class members, if any;
- That Plaintiffs and Class members paid more for their Lidoderm purchases or reimbursements than they would have in the absence of Defendants' anticompetitive agreement; and
- What Plaintiffs and Class members would have been charged in the absence of Defendants' anticompetitive agreement.

3. **Closing Arguments**

The parties will present closing arguments regarding their competing methods for measuring aggregate damages, and the findings of fact they will ask the jury to make regarding the inputs used to calculate the damages amount.

4. **Final Instructions and Special Verdict Forms**

Jurors will return special verdict forms in which they will provide the aggregate damages for each state in which the jury previously found liability. In pre-trial proceedings in advance of Phase II, Plaintiffs may draft special jury interrogatories to address the different damage remedies allowed under state law. The resulting special verdict forms will include questions for jurors to award treble or increased damages as permitted or required under state law.

C. Phase III: Damages Allocation

Aggregate damages awarded by the jury during Phase II will be allocated through an administrative process and the submission of claim forms. The allocation of damages in Phase III will not involve any issues related to Defendants or their liability, but instead concerns only issues that are internal to the Class.

After the conclusion of Phase II, Plaintiffs will submit a Claims Administration Protocol. The protocol will call for Class members to submit information to verify their generic and/or branded Lidoderm purchases during the Class period. Consumers who purchased branded Lidoderm prior to September 15, 2013 will also complete a short form to verify that they would have purchased generic Lidoderm had it been available. Third-party payors will submit claims data showing their reimbursements for purchases made by their members.

Plaintiffs anticipate recommending the appointment of allocation counsel or other designees charged with reviewing the forms and information submitted by Class members and resolving any individualized damages issues. The allocation of damages to specific class members will be guided by economic data concerning the Lidoderm payments made in each state and by category of payor. Plaintiffs will then submit an itemized report to the Court that recommends a specific damages allocation among Class members. Class members will have the opportunity to contest or comment upon the allocation recommendation prior to the Court entering final judgment.

EXHIBIT A

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

IN RE STATIC RANDOM ACCESS MEMORY (SRAM) ANTITRUST LITIGATION	Case No. 4:07-md-1819 CW MDL No. 1819
This Document Relates to: ALL ACTIONS	**[proposed] JOINT JURY INSTRUCTIONS**

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PRELIMINARY STATEMENT

All parties hereby submit their proposed jury instructions regarding the antitrust claims and defenses at issue and reserve the right to amend, supplement, or otherwise revise these instructions as appropriate following the Court's rulings on any pending or pretrial motions, a final determination as to the manner in which these cases will be tried or as is otherwise reasonable and appropriate.

PRE-TRIAL INSTRUCTIONS

No. 79 – [DEFENDANTS' PROPOSAL NO. __] THE SHERMAN ANTITRUST ACT

[DISPUTED]

As you know, the direct purchaser class has brought claims against Samsung and Cypress, and the indirect purchaser classes have brought claims only against Cypress. I will now instruct you with respect to the claims of the direct purchasers, and then I will instruct you separately with respect to the claims of the indirect purchasers.

Defendants' Argument For

This is simply a transitional instruction.

DPPs and IPPs' Argument Against

Defendants' proposed instruction about direct and indirect purchasers is unnecessary and likely to confuse the jury. To the extent the direct and indirect purchaser cases are tried together, Defendants' proposed instruction impermissibly makes reference to "direct purchasers" and "indirect purchasers," rather than simply "plaintiffs." As discussed in at least one of the direct purchaser plaintiffs' proposed instructions herein ("DAMAGES - NO PASS-ON CONSIDERATIONS"), as well as direct purchaser plaintiffs' motion *in limine*, in no portion of any direct purchaser case should the jury consider the issue of "pass-on"/"pass through," and the defendants should not be permitted to draw the jury's attention to the issue of "pass-on"/"pass though" or the distinction between direct and indirect purchasers. *See Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 489 (1968).

The instruction also unnecessarily emphasizes that Cypress is a defendant in the direct and indirect actions, and Samsung only in the direct action.

Defendants' proposed instruction is inappropriate, not supported by their cited authority, and should not be adopted.

No. 80 – [DPPs' PROPOSAL NO. __] SHERMAN ACT – PURPOSE */DISPUTED/*

Now I will discuss the federal antitrust laws that apply in this case. One of these laws is referred to as the Sherman Act. The purpose of the Sherman Act is to preserve and advance our system of free competitive enterprise by encouraging free and open competition in the marketplace by preventing unreasonable restraints on trade so that both the public and businesses may receive better goods and services at lower prices.

Authority

Adapted from: *A.D. Bedell Wholesale Co., Inc. v. Philip Morris, Inc.*, 263 F.3d 239 (3d Cir. 2001); Jury Instruction of Chief Judge Thomas F. Hogan in *In re Vitamins Antitrust Litig.*, MDL Docket No. 1285, Misc. No. 99-197 (D.D.C.) (as given on June 11, 2003, Instruction No. 27) *available as* Ex. C to Plaintiffs' Appendix; KEVIN O'MALLEY, JAY E. GRENIG & WILLIAM C. LEE, FEDERAL JURY PRACTICE AND INSTRUCTIONS § 150.01 (5th ed. 2001); ABA Antitrust Law Section, Model Jury Instructions in Civil Antitrust Cases A-2 (2005 ed.) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977), and *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)); LEONARD SAND, JOHN S. SIFFERT, WALTER P. LOUGHLIN, STEVEN A. REISS & NANCY BATTERMAN, MODERN FEDERAL JURY INSTUCTIONS, Instruction 79-2 (Vol.4 2005).

DPPs' Argument For

Plaintiffs' proposed instruction properly provides jurors with a basic framework and background so that they can understand the context of plaintiffs' claims. The instruction is a short and accurate description of the Sherman Act's purpose which does that. *See* KEVIN O'MALLEY, JAY E. GRENIG & WILLIAM C. LEE, FEDERAL JURY PRACTICE AND INSTRUCTIONS § 150.01 (5th ed. 2001) ("The purpose of the Sherman Act is: (1) to preserve and advance our system of free, competitive enterprise; (2) to encourage, to the fullest extent practicable, free and open competition in the marketplace; and (3) to prevent the accomplishment of a monopoly in any business or industry all to the end that the consuming public may receive better goods and services at a lower cost.").

Plaintiffs' proposed instruction is appropriate, supported by their cited authority, and should be adopted.

Defendants' Argument Against

As stated above, there is no need to instruct the jury on the purpose of the Sherman Act, as the purpose of the Act is not for the jury's consideration and plays no role in their consideration of the evidence or their deliberations, particularly in a case governed by the *per se* rule. *See* No. 5. The only purpose of this instruction would be to blur or undermine the elements plaintiffs are required to prove. The only questions before the jury are whether a conspiracy existed, whether defendants or alleged coconspirators were part of one, and whether the plaintiffs suffered injury and damages.

Plaintiffs' formulation also is inaccurate insofar as it fails to instruct the jury of other purposes of the antitrust laws. If adopted, it should be revised to include the following (footnotes provide the authority in support and the first two sentences are from the plaintiffs):

> The purpose of the Sherman Act is to preserve and advance our free enterprise system. It does so by encouraging free and open competition in the marketplace by preventing unreasonable restraints and restrictions on business or trade, so that both the public and businesses may receive better goods and services at lower prices. However, it recognizes that in the natural operation of the economic system, some competitors are going to lose business while others prosper.

It is sometimes difficult to distinguish robust competition from conduct with long-term anticompetitive effects.[1] The antitrust laws are not aimed at eliminating an efficient, vigorous, aggressive competitor.[2] The antitrust laws also do not require the courts to protect small businesses from the loss of profits due to continued competition, but only against the loss of profits from practices forbidden by the antitrust laws. In fact, it is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition.[3]

Even an act of pure malice by one business competitor, without more, does not establish a claim under the federal antitrust laws. The federal antitrust laws do not create a federal law of unfair competition nor do they provide remedies for all injuries committed by or against persons engaged in interstate commerce. Thus, there are many kinds of unquestionably wrongful conduct which, nevertheless, are not prohibited by the antitrust law because, however bad they may seem, they do not suppress competition in a prohibited way.[4] Acts become unlawful, therefore, only when they constitute an unreasonable restraint on interstate commerce.

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[1] *See Spectrum Sports v. McQuillan*, 506 U.S. 447, 458-59 (1993) ("The purpose of the Act is not to protect businesses from the working of the market; it is to protect the public from the failure of the market. The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself. … It is sometimes difficult to distinguish robust competition from conduct with long-term anticompetitive effects.") (citations omitted).

[2] *See United States v. Syufy Enters.*, 903 F.2d 659, 668-69 (9th Cir. 1990) ("It can't be said often enough that the antitrust laws protect competition, not competitors. … We make it clear today, if it was not before, that an efficient, vigorous, aggressive competitor is not the villain antitrust laws are aimed at eliminating.").

[3] *See Cargill, Inc. v. Monfort of Colo., Inc.*, 479 U.S. 104, 116 (1986) ("*Brunswick* holds that the antitrust laws do not require the courts to protect small businesses from the loss of profits due to continued competition, but only against the loss of profits from practices forbidden by the antitrust laws. The kind of competition that Monfort alleges here, competition for increased market share, is not activity forbidden by the antitrust laws. It is simply, as petitioners claim, vigorous competition. To hold that the antitrust laws protect competitors from the loss of profits due to such price competition would, in effect, render illegal any decision by a firm to cut prices in order to increase market share. The antitrust laws require no such perverse result, for '[i]t is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition.'") (citation omitted).

[4] *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224-25 (1993) ("Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal antitrust laws; those laws do not create a federal law of unfair competition or 'purport to afford remedies for all torts committed by or against persons engaged in interstate commerce.'") (citation omitted).

No. 81 – [DPPs' PROPOSAL NO. __] SHERMAN ACT – SECTION 1 */DISPUTED/*

Section 1 of the Sherman Act prohibits contracts, combinations or conspiracies that unreasonably restrain trade.

Authority

Adapted from: *In re Flat Glass Antitrust Litig.,* 385 F.3d 350, 356 (3d Cir. 2004); *InterVest Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 158 (3d Cir. 2003); *Rossi v. Standard Roofing Inc.*, 156 F.3d 452, 461 (3dCir. 1998); *Denny's Marina, Inc. v. Renfro Prod., Inc.*, 8 F.3d 1217, 1220 (7th Cir. 1993); Jury Instruction of Chief Judge Thomas F. Hogan in *In re Vitamins Antitrust Litig.*, MDL Docket No. 1285, Misc. No. 99-197 (D.D.C.) (as given on June 11, 2003, Instruction No. 28) *available as* Ex. C to Plaintiffs' Appendix; ABA Antitrust Law Section, Model Jury Instructions in Civil Antitrust Cases A-3 (2005 ed.).

DPPs' Argument For

Plaintiffs' proposed instruction properly and simply instructs jurors as to Sherman Act's prohibitions. *See Maxim Integrated Products, Inc. v. Analog Devices, Inc.,* 1994 WL 514024 at *2 (N.D. Cal. Sep 07, 1994) *aff'd in part, rev'd in part by Maxim Integrated Products, Inc. v. Analog Devices*, Inc., 79 F.3d 1153 (9th Cir. 1996) ("Section 1 of the Sherman Act prohibits contracts, combinations and conspiracies which unreasonably restrain trade.").

Plaintiffs' proposed instruction is appropriate, supported by their cited authority, and should be adopted.

Defendants' Argument Against

There is no need to instruct the jury on the general provisions of Section 1, and the introduction of the concept of an "unreasonable" restraint of trade may be confusing. In a *per se* case such as this, the jury's only task with regard to Section 1 is to determine whether a conspiracy existed and whether the defendants or their alleged coconspirators were part of one. If the jury finds a price-fixing conspiracy as alleged by plaintiffs, such a conspiracy is, as a matter of law, an unreasonable restraint of trade.

No. 82 – [DPPs' PROPOSAL NO. __] SHERMAN ACT – SECTION 1 – ELEMENTS

[DISPUTED]

To prove a violation of section 1 of the Sherman Act, plaintiffs must establish: (1) a contract, combination, or conspiracy; and (2) an unreasonable restraint of trade in or affecting interstate commerce.

Authority

Adapted from: *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 356 (3d Cir. 2004); *InterVest Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 159 (3d Cir. 2003); *Petruzzi's IGA Supermarkets, Inc. v. Darling-Del. Co., Inc.*, 998 F.2d 1224, 1229 (3d Cir. 1993); 5TH JUDICIAL CIR. PATTERN JURY INSTRUCTIONS (CIV. CASES) 6.1 (2006).

DPPs' Argument For

Plaintiffs' proposed instruction properly instructs jurors as to the elements plaintiffs must prove to establish a violation of Section 1 of the Sherman Act. *See, e.g, In re Flat Glass Antitrust Litig*., 385 F.3d 350, 356 (3d Cir. 2004) ("Section 1 only prohibits contracts, combinations, or conspiracies that unreasonably restrain trade").

Plaintiffs' proposed instruction focuses only on the two elements necessary to show a violation of the Sherman Act. Other instructions will discuss what plaintiffs must show to demonstrate that the restraint is unfair (e.g. presumed in *per se* price-fixing cases), as well as what plaintiffs must show to recover damages.

Having an instruction solely on the issue of violation makes particular sense here because of the distinct possibility that the jury may first be empanelled solely to render a verdict on the issue of a conspiracy in violation of Section 1 of the Sherman Act, without making any determination with respect to impact or damages.

Plaintiffs' proposed instruction is appropriate, supported by their cited authority, and should be adopted.

Defendants' Argument Against

This instruction is objectionable for the same reasons as the previous one. Introduction of the concept of an "unreasonable" restraint of trade is unnecessary and potentially confusing in a *per se* case. *See, e.g., Modern Federal Jury Instructions – Civil*, Instr. 79-3, Notes ("Because horizontal price-fixing conspiracies are *per se* unreasonable, injecting the unreasonableness concept into such a case adds little except the potential for some jury confusion."). A more accurate instruction, as submitted by Defendants below, instructs the jury on the four distinct elements that plaintiffs must prove to recover for the antitrust violation: existence of a conspiracy, participation by one or more defendants, effect on interstate commerce, and injury to the plaintiffs' business or property. Plaintiffs' version ignores at least the second element (participation/joinder) and the fourth element (causation and injury). Despite the fact that plaintiffs' three Third Circuit authorities and the Fifth Circuit Pattern Jury Instructions all recognize that causation and injury

are essential elements of plaintiffs' claim, plaintiffs nowhere have an explicit injury and causation instruction in their instructions.

Moreover, reference to a "contract" is potentially confusing, as no contract between the defendants and/or their alleged coconspirators has been alleged.

No. 83 – [DEFENDANTS' PROPOSAL NO. __] ELEMENTS OF THE OFFENSE

[DISPUTED]

To prevail against a defendant on a price-fixing claim, plaintiffs must prove as to that particular defendant each of the following elements by a preponderance or greater weight of the evidence:

First, that a conspiracy between or among at least two separate entities to fix the prices of SRAM existed from November 1, 1996 through December 31, 2005;

Second, that a defendant knowingly - that is, voluntarily and intentionally - became a party to that conspiracy with the purpose of furthering the goals of that conspiracy;

Third, that the conspiracy restrained or affected interstate commerce; and

Fourth, that the conspiracy caused the direct purchasers to suffer an injury to their business or property.

If you find that the evidence is insufficient to prove any one or more of these elements as to a particular defendant, then you must find for that defendant and against the direct purchasers on the direct purchasers' price-fixing claim. If you find that the evidence is sufficient to prove all four elements as to a particular defendant, then you must find for the direct purchaser plaintiffs and against that particular defendant on the direct purchasers' price-fixing claim.

I will now explain each of these elements in further detail.

Authority

Adapted from ABA Model Jury Instructions, B-20 (emphasis original); *see also id.* A-3, B-2, B-13; Leonard B. Sand, *Modern Federal Jury Instructions – Civil*, Instr. 79-3 (Matthew Bender, 2001) ("the plaintiff must prove, by a preponderance or greater weight of the evidence," each of the elements); *Monsanto v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984) (plaintiff must prove that the "the manufacturer and others had a conscious commitment to a common scheme designed to achieve an unlawful objective.").

Defendants' Argument For

The ABA Model Jury Instructions, B-20, recommended by the Ninth Circuit to be used for substantive antitrust jury instructions, is an accurate and balanced summary of the elements plaintiffs need to prove.

DPPs and IPPs' Argument Against

Defendants' proposed instruction contains unnecessary elements for this case, and is otherwise confusing and improper.

The instruction states at least ***four*** times that plaintiffs must prevail against "a defendant"/ "particular defendant." Such repetition is done solely to create the impression that plaintiffs must overcome several hurdles to prevail.

The instruction improperly includes misleading language about plaintiffs being able to prove their claims with a "greater weight of [] evidence" than a preponderance.

The first element in the instruction incorrectly states that plaintiff must show that the conspiracy "existed from November 1,1996 through December 31, 2005." Plaintiffs can also prevail by having the jury find that a conspiracy existed for a shorter period.

The second element's discussion of "knowingly join" would be better presented in a follow-up instruction.

The third element should be undisputed, and including it here as an element only reinforces the idea that plaintiff must overcome several hurdles to prevail.

The fourth element goes to the issue of damages, and as discussed above, a clearer presentation of instructions would be to not include impact/damages elements together with the violation elements.

Finally, defendants' instruction unduly emphasizes that the evidence may be "insufficient to prove any one or more of these elements." As with many other instructions proposed by defendants, this instruction gives, at the expense of plaintiffs, unwarranted attention to various outcomes that favor only the defendants. (The use of bolding in the instruction is also improper.)

Defendants' proposed instruction is inappropriate, not supported by their cited authority, and should not be adopted.

In addition, IP Plaintiffs hereby incorporate by reference their Arguments and Authority Against Cypress's Proposed Instruction No. 126 on this same topic.

No. 84 – [DPPs and IPPs' PROPOSAL NO. __] CONTRACT, COMBINATION OR CONSPIRACY *[DISPUTED]*

The first element plaintiffs must prove is the existence of an unlawful contract, combination or conspiracy. A contract, combination or conspiracy is found where there is some form of concerted action. There must be a unity of purpose or a common design and understanding, a meeting of the minds or a conscious commitment to a common scheme to achieve an unlawful objective.

Under the Sherman Act, it is illegal for two or more competitors to agree to fix, raise, maintain or stabilize the prices charged or to be charged for products or services. This prohibition is violated not only if the same price is set by competitors, but also if a range of prices or levels of prices are set, or if there is any tampering with free market pricing.

It is illegal for competitors to conspire to increase prices, to set a specific price or range of prices or to increase the stability of prices, including to stop prices from falling further than they otherwise would fall, or to agree to any course of conduct that effects prices.

It is also illegal for competitors to conspire to restrict or reduce or limit the market supply of a product in order to raise, maintain, or stabilize the prices of the product.

To prove a conspiracy, the evidence does not have to show that the conspirators entered into a formal, express or written agreement; or that they met together; or that they directly stated what their object or purpose was, or the details of it, or the means by which they would accomplish their purpose. You have to look to all the evidence together and determine whether the defendants and their alleged coconspirators had a unity of purpose or a common design and understanding, a meeting of the minds, to accomplish a common purpose. A "gentleman's agreement" or a "wink" or a "nod" or a tacit understanding may be sufficient.

You may find that the unity of purpose or common design and understanding is proven by circumstantial evidence and by inferences from what the defendants and their alleged coconspirators said and did or did not do.

A conspiracy may be formed without all parties coming to an agreement or understanding at the same time. A conspiracy may be formed over a period of time with different parties joining the conspiracy at different points of time. It is not essential that all conspirators act exactly alike. Evidence must be presented tending to exclude the possibility that the alleged conspirators acted independently; some of the facts you may consider in that regard are: (1) whether the conspirators' actions, if taken independently, would be contrary to their economic self-interest; (2) whether the conspirators have been uniform in their actions; (3) whether the conspirators have exchanged or have had the opportunity to exchange information relative to the alleged conspiracy; and (4) whether the conspirators have a common motive to conspire.

In viewing the evidence relating to whether there was a conspiracy and whether defendants and their alleged coconspirators were members, you are to view all the evidence collectively and as a whole. You should examine all the evidence – direct, circumstantial and economic – to determine what inferences can be drawn concerning the alleged conspiracy by looking at the evidence as a whole. You should not view the evidence in segments, compartmentalizing the various factual components. An alleged conspiracy is not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.

Authority

Adapted from: *United States v. Brodie*, 403 F.3d 123, 134 (3d Cir. 2005); *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 356-57, 362, 368-69 (3d Cir. 2004); *LePage's, Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003); *United States v. Mastrangelo*, 172 F.3d 288, 293-94 (3d Cir. 1999); *Petruzzi's IGA Supermarkets, Inc. v. Darling-Del. Co., Inc.*, 998 F.2d 1224, 1232 (3d Cir. 1993); *Nanavati v. Burdette Tomlin Mem'l Hosp.*, 857 F.2d 96, 119 (3d Cir. 1988); *United States v. Cont 'l Group, Inc.*, 603 F.2d 444, 462 (3d Cir. 1979); *Wallace v. Price*, 265 F.Supp.2d 545, 569 (W.D. Pa. 2003); *Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 771 (1984); *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809-11 (1946); *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 210-14, 218, 223-24 (1940); *In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 655-56, 661-62 (7th Cir. 2002); *City of Tuscaloosa v. Harcros Chems., Inc.*, 158

F.3d 548, 569 (11th Cir. 1998); *Systemcare, Inc. v. Wang Labs. Corp.*, 117 F.3d 1137, 1143, 1145 (10th Cir. 1997); *Wallace v. Bank of Bartlett*, 55 F.3d 1166, 1168 (6th Cir. 1995); *ES Dev., Inc. v. RWM Enters., Inc.*, 939 F.2d 547, 553-54 (8th Cir. 1991); *Int'l Distrib. Ctrs., Inc. v. Walsh Trucking Co*., 812 F.2d 786, 793-94 (2d Cir. 1987); *Pierce v. Ramsey Winch Co.*, 753 F.2d 416, 426-27 (5th Cir. 1985); *Fontana Aviation Inc. v. Cessna Aircraft Co*., 617 F.2d 478, 481 (7th Cir. 1980); *United States v. Consol. Packaging Corp.*, 575 F.2d 117, 125-28 (7th Cir. 1978); *Bowen v. Parking Auth. of City of Camden*, No. Civ. 00-5765 (JBS), 2003 WL 22145814, *37 (D. N.J. Sept. 18, 2003); *Wagner v. Magellan Health Servs., Inc.*, 121 F.Supp.2d 673, 679 (N.D. Ill. 2000); *Marcolongo v. School Dist. of Phila.*, No. Civ. A. 98–5196, 1999 WL 1011899, *9 (E.D. Pa. Nov. 5, 1999); *Smith v. Wambaugh*, 29 F.Supp.2d 222, 228 (M.D. Pa. 1998); *United States v. Palladino*, 203 F. Supp. 35, 37 (D. Mass. 1962); Jury Instructions of Judge Gary L. Lancaster in *In re Indus. Silicon Antitrust Litig*., No. 95-2104 (W.D. Pa.)(as given on May 17, 1999, N.T. 52-54, 56) *available as* Ex. A to Plaintiffs' Appendix; Jury Instruction of Chief Judge Thomas F. Hogan in *In re Vitamins Antitrust Litig.*, MDL Docket No. 1285, Misc. No. 99-197 (D.D.C.) (as given on June 11, 2003, Instruction No. 29) *available as* Ex. C to Plaintiffs' Appendix; Jury Instructions of Judge Singleton in *In re Corrugated Container Antitrust Litig.*, MDL No. 310 (S.D. Tex.) (as given on Sept. 11, 1980, Tr. Vol. 100 at 59-62) *available as* Ex. B to Plaintiffs' Appendix; KEVIN O'MALLEY, JAY E. GRENIG & WILLIAM C. LEE, FEDERAL JURY PRACTICE AND INSTRUCTIONS §§ 150.41, 150.65 (5th ed. 2001); ABA Antitrust Law Section, Model Jury Instructions in Civil Antitrust Cases B-2 to B-6, B-16, B19 to B-20 (2005 ed.); 11TH CIR. PATTERN JURY INSTRUCTIONS (CIV. CASES) 3.1 (2005); *Esco Corp. v. United States*, 340 F.2d 1000, 1006-08 (9th Cir. 1965); *United States v. Andreas*, 216 F.3d 645 (7th Cir. 2000), *reh. en banc denied,* 2000 U.S. App LEXIS 18222 (7th Cir., July 27, 2000), *cert. denied* 531 U.S. 1014 (2000); *FTC v. Superior Court Trial Lawyers Assoc.*, 493 U.S. 411,423 (1990); *Fleischman v. Albany Medical Center*, 2010 WL 2998304 *26 (N.D.N.Y., July 22, 2010).

DPPs and IPPs' Argument For

Plaintiffs' proposed instruction properly instructs jurors as to:

(1) the need for plaintiffs show that the conspirators reached an agreement. *See United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 210-14, 218, 223-24 (1940) (discussing informal "gentlemen's agreement"); *United States v. Consol. Packaging Corp.*, 575 F.2d 117, 125-28 (7th Cir. 1978) (late joiner).

(2) the various ways there can be a *per se* price-fixing violation – i.e. not just agreeing to increase prices in specific amount. *See, e.g., In re Linerboard Antitrust Litig.*, 292 F.Supp.2d 644, 660 (E.D. Pa. 2003) (restrictions on production); *United States v. Topco Assoc., Inc.*, 405 U.S. 596 (1972) (market division).

(3) that circumstantial evidence can be sufficient to show conspiracy. *See In re High Fructose Corn Syrup Antitrust Litig.*, 295 F.3d 651, 662 (7th Cir. 2002) ("[M]ost cases are constructed out of a tissue of such [ambiguous] statements and other circumstantial evidence, since an outright confession will ordinarily obviate the need for a trial."); *In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig.*, 906 F.2d 432, 447 & n.13 (9th Cir. 1990).

The instruction also properly explains what it means for circumstantial evidence to "exclude the possibility that the alleged conspirators acted independently." *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764, 768 (1984). That portion of the instruction is particularly important for this case, because competitors directly meeting or exchanging information with each other is specifically identified as one of the ways to show that the alleged conspirators were not acting independently. *See In re Flat Glass Antitrust Litig.,* 385 F. 3d 350, 361, fn. 12 (3d Cir. 2004) ("exchanges of confidential price information, cannot simply be explained as a result of oligopolostic interdependence"); *Fleischman v. Albany Medical Center*, 2010 WL 2998304 at *23-26 (N.D.N.Y., July 22, 2010) ("some of the facts you may consider in that regard are: . . . whether the conspirators have exchanged or have had the opportunity to exchange information relative to the alleged conspiracy").

Finally, the instruction informs the jurors of the need for them to consider all of the evidence together, and to not dismember and evaluate individual facts and issues separately. *See Continental Ore Co. v. Union Carbide & Carbon Corp*., 370 U.S. 690, 699 (1962) ("[P]laintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each. . . . [T]he duty of the jury is to look at the whole picture . . . ."); *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 990 (9th Cir. 2000).

Plaintiffs' proposed instruction is appropriate, supported by their cited authority, including Supreme Court and Ninth Circuit precedent, and should be adopted.

Defendants' Argument Against

To the extent relevant, the same objections discussed in plaintiffs' proposed pre-trial instruction on conspiracy apply here. *See* No. 19. As explained below, this instruction is very unbalanced and would be misleading. *See Chuman*, 76 F.3d at 294 ("Jury instructions must be formulated so that they fairly and adequately cover the issues presented, correctly state the law, and are not misleading.").

An instruction on conspiracy should not be given until the jury has been instructed on all the elements of plaintiffs' claim, per the instruction submitted by Defendants.

The reference to a "contract" is potentially confusing, as no contract has been alleged.

Plaintiffs first line regarding the existence of conspiracy omits "by or among two or more persons."

In paragraph 2, the phrase "fix, raise, maintain or stabilize prices" must normally be limited to just "fix prices." However, if plaintiffs wish to define its price fixing claim to also include "rais[ing], maintain[ing] or stabiliz[ing] prices", this instruction would be the one place to do it. The repeated references to "fix, raise, maintain or stabilize prices" in all other instructions should be struck.

The statement in the second paragraph that the prohibition is violated "not only if the same price is set by competitors, but also if a range of prices or levels of prices are set" is an incorrect

statement of the law, in that it suggests that parallel pricing alone may be a violation of Section 1. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 553 (2007) (parallel conduct does not show conspiracy under Section 1); *General Bus. Sys. v. North Am. Philips Corp.*, 699 F.2d 965, 976 (9th Cir. 1983) ("Price parallelism alone generally will not establish price fixing."); *Wallace v. Bank of Bartlett*, 55 F.3d 1166, 1168 (6th Cir. 1995) ("parallel pricing, without more, does not itself establish a violation of the Sherman Act").

The reference in the second paragraph to "tampering with free market pricing" or "any course of conduct that effects prices" are vague and misleading. To establish a violation of Section 1 through price-fixing, plaintiffs must prove an ***agreement***.

As stated previously, the statement "unity of purpose or a common design and understanding, a meeting of the minds, to accomplish a common purpose" at least needs the phrase "designed to achieve an unlawful objective."

The statement in the fourth paragraph that it is illegal to limit market supply improperly suggests that such evidence exists in this case. Plaintiffs are entitled to instructions on their theory of the case if it has foundation in the evidence, *Jenkins v. Union Pacific R. Co.*, 22 F.3d 206, 210 (9th Cir. 1994), but they are not entitled to instructions that do not fairly reflect the evidence.

The reference in the fifth paragraph to "a tacit understanding" being sufficient to prove a conspiracy is an incorrect statement of the law. It may be possible to show that an *agreement* was tacit rather than express, but the term "tacit understanding" suggests that independent conduct such as conscious parallelism — the lawful practice of firms in a concentrated industry "recognizing their shared economic interests and their interdependence with respect to price and output decisions," *see Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 227 (1993) — is also unlawful. Plaintiffs similar phrases regarding a "gentleman's agreement" or a "wink" or a "nod" are improper for the same reasons and also are vague and misleading.

Plaintiffs proposed language that a conspiracy can be "proven by circumstantial evidence and by inferences…" is inadequate and misleading as stated in Defendants' response to plaintiffs' proposed separate instructions on these topics. *See* Nos. 17, 63, 65, 66, 87. Plaintiffs' version also deletes a very important paragraph from ABA Model Jury Instructions, B-3-4 (cited by plaintiffs):

> Mere similarity of conduct among various persons, however, or the fact that they may have associated with one another and may have met or assembled together and discussed common aims and interests, does not establish the existence of a conspiracy unless the evidence tends to exclude the possibility that the persons were acting independently. If they acted similarly but independently of one another, without any agreement among them, then there would not be a conspiracy.

Defendants' instruction below (No. 85) includes this language.

The final paragraph merges the required elements of finding a conspiracy, and finding that one or more defendants were members of that conspiracy, and thus is confusing. The structure of the ABA Model Instructions, which Defendants' instructions follow, separates these separately required elements and thereby provides greater clarity.

The reference to "direct, circumstantial, and economic" evidence in the final paragraph incorrectly suggests that economic evidence should be treated as qualitatively different from other evidence.

The instruction is also repetitive in reminding the jury (yet again) for a full paragraph to view all the evidence together as a whole, and it is unbalanced in that never reminds the jury that if it finds that the evidence does not support the inference of conspiracy sought by plaintiffs, it must find for the defendants.

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEXIUM (ESOMEPRAZOLE) ANTITRUST LITIGATION	MDL No. 2409 Civil Action No. 1:12-md-02409
This Document Relates To: All Actions	

PLAINTIFFS' PROPOSED PRELIMINARY JURY INSTRUCTIONS FOR PHASE I OF TRIAL

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PRELIMINARY INSTRUCTIONS FOR USE AT BEGINNING OF TRIAL[1]

Plaintiffs respectfully request the following instructions be given to the jury at the outset of the trial. Plaintiffs reserve the right to submit additional proposed instructions of law.

PROPOSED JURY INSTRUCTION 1

1. The Hatch-Waxman Act

This case involves brand and generic drugs, and you will learn about how the United States Food and Drug Administration, or the "FDA," approves drugs. I am going to give you a brief explanation of the drug approval process to help you understand better the evidence that will be presented.

Federal law requires that drug companies apply for and obtain approval from the FDA before they can sell a drug in this country.[2] The first company to develop a drug files an application called a New Drug Application or "NDA."[3] The NDA contains technical information on the chemicals in the drug, the method of manufacturing it, and its effect on the human body.[4] The purpose of the New Drug Application is to demonstrate to the FDA that the drug is safe and effective for its proposed uses.[5]

If the FDA concludes after reviewing the application that the drug is both safe and effective, it approves the New Drug Application and allows the drug to be sold in the United States.[6] Drugs approved under the New Drug Application process are often called "brand-name

[1] Plaintiffs reserve the right to supplement and amend these proposed jury instructions.

[2] Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 301-392.

[3] Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), 21 U.S.C. § 355.

[4] 21 U.S.C. § 355(b)(1).

[5] *Id.*

[6] 21 U.S.C. § 355(c)(1)(A).

drugs" because manufacturers market them under a brand name rather than under the drug's chemical name. Nexium, the prescription drug at issue in this case, is an example of a brand-name drug. The active ingredient in Nexium is a chemical called esomeprazole magnesium, which you may hear shortened to esomeprazole.

The FDA also approves generic drugs.[7] Generic drugs have the same active ingredient as the brand drug, but are usually sold under their chemical name. If you buy Tylenol, for example, you are buying the brand name version. The active ingredient in Tylenol is acetaminophen. If you buy a bottle just labeled acetaminophen, it's the generic. The same goes for prescription drugs. Nexium is the brand name; the generic is called esomeprazole or esomeprazole magnesium.

There is a federal law you will hear about that governs how generic drugs are approved. Its full name is the "Drug Price Competition and Patent Term Restoration Act of 1984," but it is more commonly called the "Hatch-Waxman Act" or simply "Hatch-Waxman."[8] The Hatch-Waxman Act covers the requirements and procedures for determining that a generic is as safe and effective as the brand drug. As suggested by its full name, Hatch-Waxman was intended in part to encourage price competition between brand and generic manufacturers.

The Hatch-Waxman Act requires that the generic drug be essentially the same as the brand-name drug: the generic drug must contain the same active chemical ingredient as the brand-name drug, must be in the same dosage form (*i.e.*, tablet or capsule) and the same dosage strength as the brand-name drug, and must be bioequivalent to the brand-name drug.[9]

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[7] 21 U.S.C. § 355(b)(1)(B).

[8] 21 U.S.C. § 355.

[9] 21 U.S.C. § 355(j)(2).

A manufacturer gets FDA approval to market a generic drug by filing an Abbreviated New Drug Application,[10] also known as an "A-N-D-A," or an "ANDA." The generic company need not demonstrate all over again that the drug is safe and effective, as the FDA has already concluded that the brand drug is safe and effective. The generic company just needs to demonstrate that the generic drug is bioequivalent to the approved brand-name drug. "Bioequivalent" means that the generic drug has the same effect in the patient's body as the brand-name drug.[11] The generic company must also prove that it can manufacture the drug to the required specifications.[12] So that is some basic background on the requirements and procedures for establishing that a generic drug is safe and effective.

The Hatch-Waxman Act also addresses how and when brand and generic drug companies can compete with each other. Brand-drug manufacturers often assert that the brand drug, or the process for making it, is covered by one or more patents. I haven't mentioned patents yet, but you will be hearing about them in this case. A patent is a legal document issued by the United States Patent and Trademark Office, or PTO, that describes an invention and allows the patent owner to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States.[13] If a person or entity sells something without permission and it is covered by a patent, the patent owner can sue the seller for what is called "patent infringement." The person sued has a number of potential defenses, including that the patent is invalid, that it can't be enforced for certain reasons, or that there is no infringement even if the patent is valid.

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[10] 21 U.S.C. § 355(j)(2).

[11] 21 U.S.C. § 355(j)(8)(B).

[12] 21 U.S.C. § 355(j)(2)(A)(vi).

[13] 35 U.S.C. § 271.

I will explain more about patents later. For now, you simply need to understand that brand drug manufacturers often claim that sale of a competing generic drug would infringe one or more of the brand manufacturer's patents, while generic manufacturers often claim, in response, that their generic versions of brand drugs do not infringe or that the patents are not valid or enforceable, or all of the above.

To promote these kinds of patent challenges, the Hatch-Waxman Act requires that a brand manufacturer filing a New Drug Application list all of its patents that it contends would be infringed by the sale of a competing generic.[14] The list is kept in an FDA publication called the "Orange Book"[15] because it literally has an orange cover. By putting the patents in the Orange Book, the FDA is not making any judgments about whether the patents are valid or could be infringed. The FDA simply lists the patents that the brand drug manufacturers ask it to list.[16]

When a generic manufacturer submits an ANDA seeking FDA approval to market a generic version of the brand drug, the Hatch-Waxman Act requires the generic manufacturer to make one of four certifications regarding the patents that the brand manufacturer has listed in the Orange Book concerning the drug.[17] The particular type of patent certification involved in this case is known as a "Paragraph IV Certification."[18] In a Paragraph IV Certification, the generic

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[14] 21 U.S.C. § 355(b)(1).

[15] The term "Orange Book" refers to the FDA's publication formally titled "Approved Drug Products with Therapeutic Equivalence Evaluations" and specifically its Patent and Exclusivity Information Addendum, which FDA is required to update every thirty days. 21 U.S.C. § 355(j)(7)(A).

[16] *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 371 (S.D.N.Y. 2002) ("the FDA is required by law to publish the information in the Orange Book. *See* 21 U.S.C. §§ 355(b)(1) & (c)(2) ('Upon submission of patent information under [these] subsection[s], the Secretary shall publish it.'). Hence, the FDA's actions are non-discretionary and do not reflect any decision as to the validity of the representations in an Orange Book listing.").

[17] 21 U.S.C. § 355(b)(2)(A).

[18] 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

manufacturer certifies that, although the brand manufacturer has listed certain patents in the Orange Book with respect to the brand drug, selling the generic drug before those patents expire will not infringe the patents because the patents are not valid or enforceable or simply do not cover the generic drug.[19]

Under the Hatch-Waxman Act, within 45 days after receiving notice of the Paragraph IV Certification, the brand manufacturer can bring a patent infringement lawsuit against the generic manufacturer in federal court.[20] That federal court will then decide who is right: are the patents valid and infringed, or not?

If the brand manufacturer brings a patent infringement lawsuit within 45 days, the Hatch-Waxman Act provides that the FDA cannot approve the generic drug for 30 months or until the patent lawsuit is over, whichever happens first.[21] You may hear the lawyers or witnesses referring to this as the "30-month stay" – because final FDA approval of the generic drug is "stayed" – or held up – for up to 30 months. At the end of the 30-month stay, however, the FDA may approve an ANDA even if the patent lawsuit has not ended or settled. If this happens, the generic manufacturer may choose to launch its generic product "at risk"—that is, at risk of later losing the infringement case. Losing an infringement case after launching at risk can result in significant liability for the generic manufacturer, as damages typically are calibrated by the amount of its at-risk sales.[22]

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[19] *Id.*

[20] 21 U.S.C. § 355(c)(3)(C).

[21] *Id.* If the brand company sues after 45 days, it does not get the benefit of the 30-month stay.

[22] *In re Nexium (Esomeprazole) Antitrust Litig.*, MDL No. 02409, 2014 WL 4370333 (D. Mass. Sept. 4, 2014). *See also* 35 U.S.C. § 271(e)(4)(C) (providing that damages may be awarded "only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug"); 35 U.S.C. § 284 (providing for "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer").

In passing the Hatch-Waxman Act, part of what Congress wanted to encourage is for generic manufacturers to challenge the validity and applicability of patents on brand drugs. Congress understood both that some brand patents are invalid and that generic companies can develop generics that do not infringe the patents even if they are valid. Congress wanted to give generic drug companies a financial incentive to do the work needed to challenge brand drug patents and demonstrate that they are invalid, or invent around them, which means developing a generic that does not infringe.[23] So Congress created a kind of reward to encourage generic manufacturers to challenge brand patents.[24]

You will hear the lawyers and witnesses refer to this reward as the "180-day exclusivity." Here is how it works: the first generic manufacturer that files a Paragraph IV Certification with respect to a particular brand drug can get a period of 180 days (six months) as the only ANDA-approved version of that drug on the market.[25] The Hatch-Waxman Act prohibits the FDA from granting approval of any other manufacturer's ANDA for that drug until 180 days after the first generic manufacturer that filed a Paragraph IV Certification enters the market.[26]

This 180-day period of exclusivity can be very valuable. In some cases, it can even be worth hundreds of millions of dollars, depending on the sales of the corresponding brand drug.[27] The reason that the generic company often can earn so much during a six-month period of exclusivity is that a generic company with 180 days of exclusivity will be the only generic on the market for six months and, during that time, it will get all of the generic sales. As a result, it will

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[23] H.R. REP. NO. 98-857, pt. 1, at 14-15 (1984) *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647.

[24] *Id.*

[25] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

[26] *Id.*

[27] *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013) ("[T]his 180-day period of exclusivity can prove valuable, [potentially] worth several hundred million dollars.'").

generally be able to charge a higher price for its generic product during the period of exclusivity than if it had to compete against other generic manufactures. You'll hear testimony about how competition from additional generics can lower prices, but for now it is sufficient to understand why those six months can matter so much.

The first Paragraph IV filer gets this 180-day exclusivity regardless of when it enters the market: the first-filer gets the 180-day exclusivity if the 30-month stay expires and it launches; it gets the exclusivity if it does not launch but waits until after the court decides the patent case; and in many circumstances it gets the 180-day exclusivity even if it settles the patent case rather than winning it at trial.[28]

When I just described the 180-day exclusivity, I was very careful to say that it only prevents the FDA from granting approval to any other manufacturer's *ANDA* during that period. The 180-day exclusivity does *not* apply to the brand company itself. The brand company can keep selling its own brand drug during the 180 day period and afterwards. A brand company can also decide to sell what is called an "authorized generic."[29] An authorized generic is the brand drug, sold by the brand company or by another company that the brand company authorizes, but with a generic label and usually at generic prices. The brand can sell an authorized generic whenever it wishes to, but it usually does not start selling one until a competing generic company is ready to launch its generic. The reason is that if the brand company launched the authorized generic before it faced competition, the brand company would just be taking branded sales from itself.

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[28] 21 U.S.C. § 355(j)(5)(B)(iv)(I). *See also In re Nexium (Esomeprazole) Antitrust Litig*., MDL No. 02409, 2014 WL 4370333, at *6 (D. Mass. Sept. 4, 2014) ("Because no other manufacturer may launch a product until 180 days after the first filer has done so, a first filer's delay effectively delays all of its competitors' entries, creating a bottleneck in the market that postpones the date on which any generic product will become available.").

[29] *Teva Pharm. Indus. v. FDA*, 410 F.3d 51, 54 (D.C. Cir. 2005); 21 U.S.C. § 355(t)(3).

You will hear testimony regarding other aspects of this 180-day exclusivity – for example, under certain circumstances the Paragraph IV first-filer might in effect transfer that exclusivity right to another generic manufacturer.[30] The Paragraph IV first-filer may also give up or "relinquish" its exclusivity; once the 180-day exclusivity is relinquished, it is no longer a barrier preventing other generic applicants from obtaining final approval.[31]

[30] Letter from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Bert W. Rein, Wiley Rein & Fielding LLP (Jul. 2, 2004) (responding to Citizen Petition at Docket No. 2004P-0227), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2004-P-0014-0002 (follow "View Attachment" hyperlink)

[31] *Id.* at 4-5.

PROPOSED JURY INSTRUCTION 2

2. Patents

I want to tell you a bit more about patents. As I mentioned, a patent is a legal document issued by the PTO that describes an invention and allows the patent owner to file a lawsuit seeking to exclude other manufacturers from making, using, offering to sell, or selling the claimed invention within the United States without the patent owner's permission.[32] If a court finds a patent to be "valid" and "infringed" – concepts that I will address in a moment – the court can order the infringer not to make, use, or sell the invention,[33] or it can award damages to the patent holder if the infringer has already begun making, using, or selling the invention.[34] If, however, the court finds the patent invalid or not infringed, the patent holder is not entitled to damages or to keep the accused product out of the market.

To get a patent, an applicant files an application with the PTO. The application includes what is called a "specification," which contains a written description of the alleged invention explaining what the alleged invention is, how it works, how to make it, and how to use it.[35] The specification concludes with one or more numbered sentences that are called patent "claims."[36] If the PTO eventually grants a patent to the applicant, the claims at the end of the patent define the boundaries of its protection and give notice to the public of those boundaries.[37]

Employees of the PTO called "patent examiners" review all patent applications to determine whether or not the claims are appropriate for patent protection – whether the claimed

[32] 35 U.S.C. § 271; 35 U.S.C. § 2.

[33] 35 U.S.C. § 283.

[34] 35 U.S.C. § 284.

[35] 35 U.S.C. § 112.

[36] 35 U.S.C. § 112(b).

[37] *Id.*

invention is, for example, truly new – and whether or not the specification adequately describes the invention claimed.[38]

After evaluating the application,[39] the examiner informs the applicant in writing of what the examiner has found and whether the examiner considers any claim to be patentable and, thus, "allowed." If the examiner instead "rejects" the claims,[40] the applicant has an opportunity to respond to the examiner to try to persuade the examiner to allow the claims as stated, to change the claims or to submit new claims.[41] This process may go back and forth for some time until the examiner concludes either that the application meets the requirements for a patent and the PTO should issue the patent, or that the application does not meet the requirements and the PTO should not issue the patent.[42]

When the patent applicant is trying to convince the examiner to issue the patent, no one is there at the patent office opposing the applicant. It's not like here in court, where you will hear lawyers and witnesses for both sides. When the patent office is looking at a patent application, there is no one there arguing that the PTO should not issue the patent because the claimed invention is not really new or for some other reason. The process is conducted without an adversary presenting arguments against what the applicant is asserting.[43]

Because of this, Congress provided in the patent statute that a patent issued by the PTO can subsequently be challenged in federal court. And in a court, there is an adversary who can present the other side of the argument, which can be an argument not presented to the

[38] 35 U.S.C. § 271; 35 U.S.C. § 102.

[39] 37 CFR 1.104(a)(1); Manual of Patent Examining Procedure ("MPEP") §§ 704.01, 707(a)(1).

[40] 35 U.S.C. § 132; MPEP § 704.01(c).

[41] 35 U.S.C. § 132.

[42] 37 CFR 1.104(a)(1); MPEP § 707(a)(1).

[43] 37 CFR § 1.902-1.997 (providing for *inter partes* review of patents only post-issuance).

examiner.[44] A patent owner who wants to enforce its patent against competitors or others can also bring a lawsuit in federal court to enforce the patent.[45] In patent-enforcement lawsuits, the patent owner must prove that the patent claims cover the accused activity or product.[46] When the patent claims cover the accused activity or product, this is called "infringement."[47]

To carry its burden of proving infringement, the patent owner must prove that each aspect of the asserted patent claim is present in the accused product or process.[48] For example, if the patent claims an invention consisting of elements 1, 2, 3, 4, and 5, the accused product does not infringe if it has only elements 1, 2, 3, and 4.[49] If even a single aspect of the patent claim is missing from the accused product or process, there is no infringement of that claim and the patent owner loses the lawsuit with respect to that claim.[50] A person accused of infringement has the right to present evidence, including expert evidence, to establish that the patent claim does not in fact cover the accused product and that it therefore does not infringe the patent.[51]

If the patent owner carries its burden of proving infringement of one or more of the patent's claims, the accused infringer can still win the patent case by proving that the patent claim is invalid.[52] Patents can be shown to be invalid. Examiners are human and sometimes make mistakes or fail to uncover or appreciate the significance of the technology that existed

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[44] 35 U.S.C. § 281; 28 U.S.C. § 1338.

[45] *Id.*

[46] *Under Sea Industries, Inc. v. Dacor Corp.*, 833 F. 2d 1551, 1557 (Fed. Cir. 1987) ("The burden always is on the patentee to show infringement").

[47] 35 U.S.C. § 271(a).

[48] *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935-36 (Fed. Cir. 1987) (en banc), *overruled on other grounds, Cardinal Chem. Co. v. Morton Intern., Inc.*, 508 U.S. 83 (1993).

[49] *Id.*

[50] *Id.*

[51] 35 U. S. C. §282(b)(1).

[52] 35 U. S. C. §282(b)(2).

before the applicant's claimed invention. Sometimes the law changes such that the legal standards applied by the examiner are different from the legal standard applied in court. Also, while only the applicant appears before the PTO when applying for a patent, accused infringers have the right to present evidence in court, including expert evidence, to establish that the alleged invention does not meet the relevant requirements and therefore the patent claims are invalid.

If the patent owner proves infringement and the accused infringer fails to prove that the patent is invalid, then the patent owner wins the patent lawsuit.[53] If, however, the patent owner fails to prove infringement and/or the accused infringer succeeds in proving the patent invalid, then the accused infringer wins the lawsuit. In that event, the accused infringer can begin selling the product (or continue selling it) without any risk of owing damages to the patent owner. Also, if the accused infringer gets a ruling from the federal court that the patent is invalid, that ruling applies in favor of everyone against whom the patent owner might try to assert it.[54] In other words, the patent is deemed to be invalid against not just the accused infringer who won the particular lawsuit, but against everyone.[55] The patent is invalid – period.

These basic principles of patent law work together with the specific Hatch-Waxman Act provisions that I already described to you. For example, recall these specific provisions of the Hatch-Waxman Act: (1) that are applicable to the pharmaceutical patents that are in the background of this antitrust case: the brand manufacturer must list the relevant patents in the Orange Book;[56] (2) the generic manufacturer can file a Paragraph IV Certification with respect to

[53] 35 U.S.C. § 282.

[54] *Blonder-Tongue Lab. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

[55] *Id.*

[56] 21 U.S.C. § 355(b)(1).

them;[57] (3) the brand manufacturer can get an automatic 30-month stay preventing the generic from entering the market by suing the generic within 45 days;[58] (4) the generic manufacturer can enter the market after the 30 months; (5) the first generic manufacturer to file a Paragraph IV Certification can get the 180-day ANDA exclusivity; (6) and the 180-day exclusivity cannot stop a brand company from selling its own authorized generic at any time.[59]

Within this specific framework, the general patent principles that I have just outlined apply: the PTO issues patents without any advocate on the other side; to enforce the patent, the patent owner can bring a lawsuit in federal court where the patent is subject to challenge;[60] in that lawsuit the patent owner has the burden of proving infringement;[61] the accused infringer can try to prove that the patent is invalid;[62] if the patent owner wins, it can ask the court to prevent the accused infringer from making, using, or selling the product and, if the accused infringer has already entered the market, can ask for damages; if the accused infringer wins, it can enter (or continue) in the market without any risk of patent damages; and if the accused infringer wins by proving that the patent is invalid, that finding of invalidity benefits everyone who wants to make, use, or sell the product.[63]

[57] 21 U.S.C. § 355(b)(2)(A); 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[58] 21 U.S.C. § 355(c)(3)(C).

[59] 21 U.S.C. § 355(j)(5)(B)(iv)(I).

[60] 35 U.S.C. § 281; 28 U.S.C. § 1338.

[61] *Under Sea Industries, Inc. v. Dacor Corp*., 833 F. 2d 1551, 1557.

[62] 35 U. S. C. §282(b)(2).

[63] *Blonder-Tongue Lab. v. Univ. of Ill. Found*., 402 U.S. 313, 350 (1971).

PROPOSED JURY INSTRUCTION 3

3. Settlement of Pharmaceutical Patent Infringement Litigation

Specific to this case, the patents that AstraZeneca listed as covering Nexium "may or may not be valid, and may or may not be infringed. A valid patent excludes all except its owner from the use of the protected process or product. And that exclusion may permit the patent owner to charge a higher-than-competitive price for the patented product. But an invalidated patent carries with it no such right. And even a valid patent confers no right to exclude products or processes that do not actually infringe."[64]

The defendants in this action are AstraZeneca, Ranbaxy, Teva, Dr. Reddy's, and various corporate affiliates of these companies. Ranbaxy, Teva and Dr. Reddy's may also be referred to as the "Generic Defendants" because these companies are in the business of selling generic drugs. You may also hear Dr. Reddy's referred to as "DRL."

You will hear evidence in this case that AstraZeneca settled patent cases that it filed against Ranbaxy, Teva and Dr. Reddy's alleging infringement of patents that allegedly claimed Nexium. Plaintiffs here are purchasers of Nexium and are, broadly speaking, alleging that all four defendants violated the antitrust laws by these settlements. "Antitrust" refers to competition, and so alleging that a defendant has violated the antitrust laws means that they are alleged to have harmed competition. I will explain more about this later, but for now, you should understand that patent related settlements can sometimes violate the antitrust laws.[65]

[64] *Actavis*, 133 S. Ct. at 2231 (citations, emphases, and original alterations omitted).

[65] *Actavis*, 133 S. Ct. at 2232.

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: October 14, 2014

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